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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,935	01/25/2002	Zairen Sun	16U 107 R1	6950

23599 7590 01/28/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,935	Applicant(s) Sun et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 5, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above, claim(s) *9-27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8 and 28-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Declaration and Amendment filed October 30, 2003 in response to the Office Action of July 20, 2003 is acknowledged and has been entered. Previously pending claims 1-5 and 7 have been amended. New claims 28-32 have been added. Claims 1-8, 28-32 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 101

4. Claims 1-8 remain rejected under 35 USC 101, and new claims 28-32 are rejected under 35 USC 101 for the reasons previously set forth in the paper mailed July 30, 2003, section 7, pages 3-17.

Applicant argues that the asserted utility of the claimed polynucleotide as being over-expressed in breast tissue is adequate to meet the utility requirement of 35 USC 101 and that the MPEP states that in most cases an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement and a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of 35 USC 101..... unless there is a reason for one skilled in the art to question the objective truth of the statement of utility. Office personnel should not begin by questioning the truth of the statement of utility, instead, the inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the

applicant. The argument has been considered but has not been found persuasive because the specification does not disclose whether it is the polypeptide or the polynucleotide which is overexpressed, the specification does not disclose any evidence that would indicate which molecule is overexpressed and given the lack of guidance in the specification it is not possible to assess specific, substantial, well established or credible utility in the absence of reasonable assumptions which Examiner did make in order to examine the claims. Given the reasonable assumptions, for the extensive reasons of record Examiner properly found that neither the polynucleotide nor the polypeptide disclosed in the specification had utility. Examiner invited Applicant to submit objective evidence demonstrating that SEQ ID NO:1 is overexpressed in breast cancer tissue as compared to normal breast tissue in order to overcome the rejection over 35 USC 101. The Sun Declaration appears to disclose such objective evidence, but since it is unsigned, it is not persuasive and the rejection is maintained for the reasons of record. Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

5. Claims 1-8 remain rejected and new claims 28-32 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 30, 2003, section 9, page 18.

Because it appears that applicant did not distinctly and specifically point out the supposed errors in the rejection, the rejection is maintained.

6. Claims 1-8 remain rejected and new claims 28-32 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 30, 2003, section 10, pages 18-22.

Applicant argues that claims 3 and 4 have been amended to recite the term "human". Applicant points to page 5, lines 9-12 and states that the specification states that the term 'human' indicates that the polynucleotide is naturally-occurring and obtained from natural sources and the specification provides ample guidance for selecting other human alleles of the SEQ ID NO:1 from naturally-occurring sources. Further, the claims are now to full length human Urb-ctf.

The arguments have been considered but have not been found persuasive as drawn to claims 5-8 and 28-32 because Applicant has not distinctly and specifically point out the supposed errors in the rejection of those claims. Further, the arguments are not persuasive as drawn to claims 3 and 4 because a review of page 5, lines 9-12 reveals support for a mammalian polynucleotide or fragment thereof having a nucleotide sequence obtainable from a natural source, i.e. the species name indicates that the polynucleotide is obtainable from a natural source. Natural sources therefore include naturally occurring normal, naturally occurring mutant, and naturally polymorphic alleles, differentially spliced transcripts, spliced variants, etc. Thus, the amendment of the claims to include the term human has broadened the scope of the claims to include mutants, polymorphic alleles, differentially spliced transcripts, spliced variants. As previously set forth in Bork, of record, alternative splicing may drastically modify function of gene products, thus one would not know how to use the broadly claimed "human" polynucleotides and

undue experimentation would be required. Further, as drawn to naturally polymorphic alleles, that is allelic variants, one would not know how to use those variants because, Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlag, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, in view of the teachings of Bowie et al, Lazar et al, Burgess et al, it could not be predicted that the broadly claimed polynucleotides would encode polypeptides that would function in the same manner as SEQ ID NO:2. Given the above, it would require undue experimentation in order to use the broadly claimed invention.

Applicant further argues that the discussion of "complement" on pages 18-19 is not understood and it is the undersigned's understanding that it is acceptable to claim a sequence and then to claim the complement to it. The normal meaning of the term covers 100% complementarity and there are a legion of patents which use the term in this precise way. The argument has been considered but has not been found persuasive for the reasons clearly set forth on pages 18-19 of the previous office action. Although Applicant reads the term to cover 100% complementarity, given the lack of definition of the term, given the art recognized understanding that a complement may be partial or it may be complete, the claims read on not only 100% complementarity but also partial complementarity. Further, each case is examined on its own merits and the rejection drawn to "complement" is proper for the reasons set forth previously. Applicant is invited to amend the claims, for

example, to recite "or the complete complement thereof" in order to obviate the rejection drawn to "complement".

It is noted that Applicant did not address the issues raised by Examiner drawn to claims 7-8 which as currently constituted read on polynucleotides which do not include a sequence that encodes more than a single amino acid of SEQ ID NO:2, did not address the issues raised by Examiner drawn to claims 5-8, 29-32 which are drawn to variants of SEQ ID NO:1, polynucleotides encoding fragments of SEQ ID NO:2 that are variants of SEQ ID NO:2.

7. Claims 1, 2, 5-8, remain rejected and new claims 28-32 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 30, 2003, section 11, pages 22-25.

Applicant argues that Applicants have disclosed a full-length open reading frame for human Urb-ctf in addition this polynucleotide also encompasses 5' and 3' sequences and the Written Description Guidelines state clearly that such disclosure complies with the written description requirement. Similarly, applicant should be able to claim fragments of it and the rejection should be withdrawn. The arguments have been considered but have not been found persuasive because although the Written Description of SEQ ID NO:1 is clear, for the reasons of record, the specification does not provide adequate Written Description of polynucleotides comprising a polynucleotide sequence encoding one, two amino acids set forth in SEQ ID NO:2 as claimed in claims 5-8 and 29-32, polynucleotides comprising polynucleotide sequence encoding polypeptides comprising fragments of SEQ ID NO:2 as claimed in claim 6, unidentified complements of a polynucleotide encoding

SEQ ID NO:2/SEQ ID NO:1 as claimed in claims 1, 2. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

8. Claims 1, 6 remain rejected under 35 USC 102(b) and claim 28 is rejected under 35 USC 102(b) for the reasons previously set forth in the paper mailed July 30, 2003, section 12, page 26.

Applicant argues that the claim 1 has been amended to recite that the polynucleotide sequences code without interruption for amino acids 1-614 as set forth in SEQ ID NO:2 or a complement thereto. This sequence is not disclosed in the cited Catalog pages and therefore it is incumbent upon the examiner to withdraw this rejection. The argument has been considered but has not been found persuasive because the claim is not limited to the complete complement of the polynucleotide that codes for amino acids 1-614 of SEQ ID NO:2, but rather is drawn to a complement thereto. A subset of the 6mers of Boehringer Mannheim Catalog meet the limitations of the claims for the reasons of record. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Applicant argues that claim 6 recites amino acids 1-263 or 459-614 of SEQ ID NO:2, which sequences are not disclosed in the cited Catalog pages. The argument has been considered but has not been found persuasive because the claim is not limited to the said sequences, but rather is drawn to a complement thereto. A subset of the 6mers of Boehringer Mannheim Catalog meet the limitations of the

claims for the reasons of record. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Applicant states that claim 12 has been withdrawn and Applicant assumes that its inclusion in the rejection was inadvertent. Examiner appreciates Applicant pointing out this inadvertent typographical error and apologizes for any inconvenience.

9. Claims 5, 7 remain rejected under 35 USC 102(b) for the reasons previously set forth in the paper mailed July 30, 2003, section 14 page 27.

Applicant argues that Konno et al do not disclose or suggest a polynucleotide comprising a polynucleotide sequence as claimed or complements thereof, consequently the cited reference can not anticipate the claim and the rejection should be withdrawn. The argument has been considered but has not been found persuasive because Applicant has not presented any evidence that established that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. The burden was on the applicant to prove that the claimed product is different from that taught by the prior art and to establish patentable differences. Since it appears that Applicant has chosen not to submit said evidence, the rejection is maintained. The arguments have been considered but have not been found persuasive and the rejection is maintained.

New Grounds of Refection

Claim Rejections - 35 USC § 112

10. Claims 3-4 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The

limitation of "a polynucleotide having 97% or more nucleotide sequence identity..... which codes without interruption for a full-length human Urb-ctf....." has no clear support in the specification and the claims as originally filed. A review of the specification did not disclose support for a "full-length human Urb-ctf which has 97% or more nucleotide sequence identity to SEQ ID NO:1, didn't provide support for how long such a "full-length" Urb-ctf is expected to be. The subject matter claimed in claims 3-4 broadens the scope of the invention as originally disclosed in the specification.

11. All other objections and rejections recited in the paper mailed July 30, 2003 are withdrawn.

12. No claims allowed.

13. Applicant's amendments necessitated the new grounds of rejection, therefore, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Susan Ungar
Primary Patent Examiner
January 21, 2004